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Radioactive News

For Radioactive Material Licensees in North Dakota North Dakota Department of Health

The Inspector's Perspective *by Justin Griffin*

Introduction

Some radioactive material licensees feel that no matter how hard they work to maintain regulatory compliance, radiation safety oversight inspectors will always find some violation in the licensee's operations. This probably happens both in states regulated by the U.S. Nuclear Regulatory Commission (NRC) and in "Agreement States" like North Dakota even though we strive for a personal relationship with our licensees.

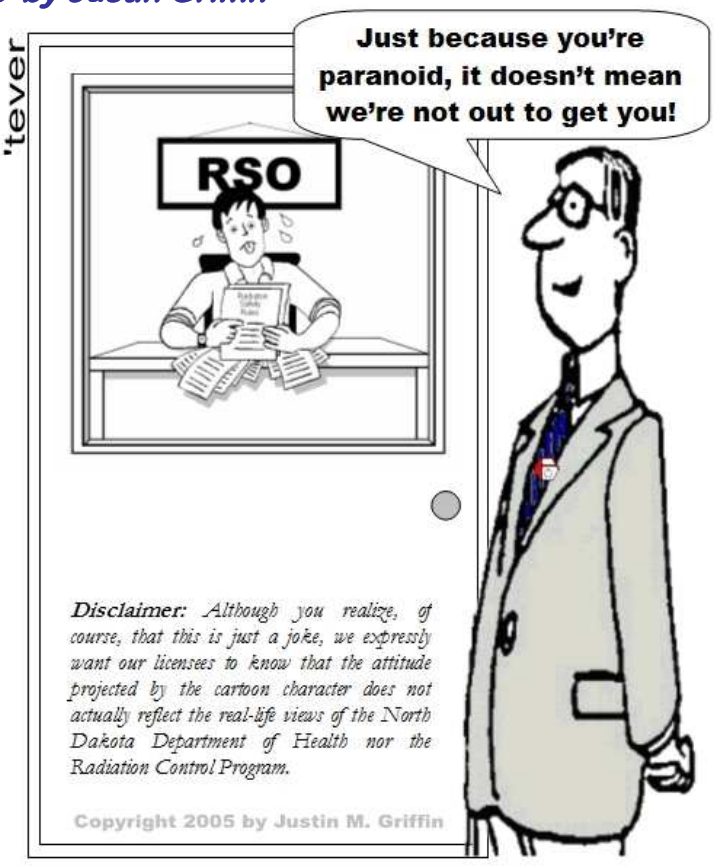
In either case, no matter how it may appear, regulators are not out to get you. It is certainly not the intention of the regulatory inspector to "dig-up" any unwarranted violations. Regulations are extensive and difficult to read, much less understand. This may lead to the inspector citing a violation thought by the licensee to be obscure, redundant or questionable.

The oversight inspection process, either by the state or the NRC, is performed with the licensee's best interests in mind. It is designed not only to ensure compliance but also to prevent unnecessary radiation exposure to radiation workers and the public and to perform vital, public health functions guided by the agency's established regulatory philosophy.

Goals of the Regulatory Agency

If you take a moment to think about the duties and responsibilities of a regulatory agency, you will notice that in addition to ensuring regulatory compliance, they strive towards three major goals:

1. Occupational Health & Safety – involving the protection of workers using licensed radioactive materials and employees working in the vicinity of radioactive material use or storage areas.



2. Public Health & Safety – involving the minimization of danger to members of the public caused by the licensed use, transportation or storage of radioactive materials.

3. Protection of the Environment – striving to minimize potential impact to nature and the environment caused by the use of licensed radioactive material

Consequently, you can see that the regulatory agency's primary mission for oversight of radioactive material is to protect the health and safety of citizens and to protect the environment from the effects of radiation due to any entity authorized to manufacture, produce, transfer, receive, acquire, own, possess,

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store or use radioactive material. In order to accomplish these goals, regulatory agencies enact a regulatory process that includes the development of rules and guidelines, as well as the use of routine compliance audits or inspections.

The Regulatory Process

The goals of the regulatory agency are achieved through the regulatory process. In a general sense, the regulatory process has five main components when it comes to radioactive material oversight. The regulatory agency will:

1. Develop regulations and guidance for radioactive material applicants or licensees.
2. Review and approve specific license applicants to use radioactive material in accordance with the limitations set forth in the regulations, guidance material and the license itself.
3. Oversee licensee operations and facilities to ensure that the licensee complies with established safety requirements and operates according to its specific license.
4. Evaluate operational experience at the licensed facilities or during licensed activities by performing routine oversight audits.
5. Effectively communicate concerns regarding the observed status of regulatory compliance and provide recommendations to improve the overall radiation safety of licensed operations.

With the advent of the Internet, appropriate regulations, guidance material and other useful resources are easily available to licensees or license applicants. This material should be reviewed periodically and assimilated into policies and procedures to ensure the safe and lawful use of radioactive material.

SAY WHAT?

That's the biggest fool thing we've ever done. The bomb will never go off; and I speak as an expert in explosives. (Admiral William Leahy's opinion on the atomic bomb, to President Truman on April 24, 1945.)

If the regulatory agency determines that the licensee is not safely conducting an activity or safely operating a facility, the agency will identify problem areas and ensure that they are addressed by the licensee. Failure to correct a problem or address an area of concern may result in escalated enforcement action. Therefore, corrective actions by the licensee should be swift and well documented.

Preparing for the Audit

Oversight audits (or inspections) are an important element of the regulatory process. The regulatory agency must conduct routine inspections to ensure that licensees meet the established regulatory requirements and operate according to the limitations of their radioactive material license.

These audits will be commensurate with the scope of the licensee's program. For example, the audit of a major university will be much more complicated than the audit of a gauge company using a single sealed source of radioactive material.

Routine inspections may be either announced or unannounced. Regulatory agencies will opt for unannounced inspections whenever possible, and each licensee must afford the inspector (at all reasonable times) the opportunity to inspect sources of radiation and the premises and facilities wherein such sources are used or stored. Licensees must make documents and records pertaining to their radiation safety programs available for review upon reasonable notice as well.

During the oversight audit, evaluation of a licensee's program will be based on direct observation of activities involving radioactive material and interviews with radiation workers and other staff. The inspector also may ask workers to demonstrate specific tasks if they will not otherwise be observed during the inspection. The inspector may perform independent measurements of radiation fields or check for contamination in locations where licensed material is used and stored at the facility, if applicable.

Most regulatory agencies have adopted this method of "inspecting for performance" (e.g., by direct observations, interviews, etc.) rather than exclusive

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NOTICE:

Some quantum physics theories suggest that when the consumer is not directly observing this document, it may cease to exist or will exist only in a vague and undetermined state. Once again, the publisher is not responsible for any inconvenience that may result.

reliance on a review of records. The inspector will undoubtedly review a random sample of records to verify that proper documentation is maintained as required. Therefore, documents relating to your radiation safety program should be clearly marked and filed in an organized manner for easy reference, not only by the inspector, but by your staff, as well.

The structure and the emphasis of the regulatory agency's oversight audit will be focused mainly on the following basic review areas:

- Security and control of licensed material – The licensee should control access to and prevent loss or theft of licensed material in use, transportation or storage unless under constant surveillance by authorized personnel.
- Shielding of licensed material – The licensee should maintain shielding of licensed material in a manner consistent with operating procedures and design and performance criteria for the sources, devices and equipment used.
- Comprehensive safety measures – The licensee should implement comprehensive safety measures to limit other hazards from compromising the safe use, transportation and storage of licensed material.
- Radiation dosimetry program – The licensee should implement a radiation dosimetry program to accurately measure and record radiation doses received by workers or members of the public as a result of licensed operations. Establishment of, or breadth of, the dosimetry program will vary depending on the scope of licensed activities, but all licensees should strive to keep radiation exposures ALARA (as low as reasonably achievable).
- Radiation instrumentation & surveys – The licensee should have access to appropriate radiation detection instrumentation in sufficient number, condition and location to accurately monitor radiation levels in areas where licensed material is used and stored.
- Radiation safety training and practices – The licensee should ensure that the appointed radiation workers are:
  - Knowledgeable about radiation uses and appropriate safety practices.
  - Skilled in applying radiation safety practices under normal and accident conditions.
  - Empowered to implement the radiation safety program and make improvements as needed.
- Management oversight – The licensee's management system should be appropriate for the scope of use and should ensure:
  - Full awareness of the radiation protection program and its importance to worker safety.
  - That audits for ALARA (as low as reasonably achievable) practices are performed.
  - That assessments of past performance, present conditions and future needs are performed and that appropriate corrective actions are taken when needed.

Prior to visiting a licensee's facility, the inspector will have reviewed your license file, including results from the previous inspection. The inspector normally will use a prepared checklist during the audit. This checklist helps the inspector perform the audit in a more organized, efficient fashion and provides a place to record comments and recommendations during the visit.

Note: *Most regulatory agencies will provide blank copies of these field audit checklists to licensees upon request. You may then review and copy these checklists to use them while performing your own internal audits annually.*

The inspector will examine the licensee's activities back to the date of the previous inspection. However,

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concerns prior to the last inspection – such as repetitive violations, incidents or high radiation exposures – also may be reviewed by the inspector during the audit. If the same violations occur year after year, the regulatory agency may choose to escalate its enforcement activity to ensure that the licensee ultimately corrects these repetitive violations.

Since radioactive material licensees are required to perform an internal audit of their own radiation safety programs annually, licensees' radiation safety officers and management should be well aware of any discrepancies and necessary improvements. Taking the time to correct these self-identified problems prior to the regulatory audit will make the job of the agency inspector easier and demonstrates that you are committed to radiation safety while actively maintaining regulatory compliance.

An inspection of your facility and operations by the regulatory agency should not be seen as a penalty for having a radioactive material license. Instead, take the opportunity to ask questions, learn what other similar facilities are doing and discuss ways to improve aspects of your radiation safety program with the inspector.

It is important to note that the licensee cannot exonerate itself by citing the regulatory agency's failure to observe violations during prior audits. It is the licensee's responsibility to ensure compliance with applicable regulatory requirements. Radioactive material licensees cannot rely solely on the regulatory agency's inspectors to achieve this end. Individual inspectors may focus on a few key aspects during one inspection and may examine other criteria during subsequent inspections; and different inspectors may scrutinize different characteristics of the licensee's program.

When licensees take an active role in maintaining compliance and continually improving on their own, the regulatory agency knows that they are most likely conducting safe operations that protect the public and the environment from any undue radiation risk.

Relationship With the Inspectors

Contrary to belief of some licensees, state and NRC inspectors are people, too. It is important for licensees to build professional relationships with the inspectors and other individuals in the regulatory agency.

For example, in North Dakota's Radiation Control Program, each compliance inspector is responsible for about 30 licensees. If the radiation safety officers from my 30 licensees were in a room together, I would be able to place each person with the name of his or her respective company. This familiarity with members of the regulated community helps an inspector to relate to their situations more efficiently and provides quicker insight into questions, problems and concerns licensees may face on the job.

From the other side, most of the licensees in our state are personally familiar with at least one, if not two, state inspectors. As an important part of the regulated community, it is crucial for these individuals to be familiar enough with the inspectors to trust and respect them.

Licensees should contact the regulatory agency personnel whenever they have questions regarding regulations, guidance material or actual aspects of their licensed activities. Regulatory personnel will assist licensees with any questions that arise. Sometimes we may not know the answer immediately, but we have numerous resources available from which to draw information and will either work toward providing the appropriate answer or relay your inquiry to a more qualified individual.

The licensee's active involvement in continuous improvement of the licensed radiation safety pro-

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Blast from the Past

September 15, 1980 – Grand Forks AFB

A B-52 carrying nuclear-armed short range attack missiles caught fire while on the ground during an alert exercise. Firefighters managed to keep the intense flames away from the missiles. The fire was caused by a fuel leak, burned intensely for more than three hours and was extinguished only after the fuel flow had ceased.

(Source: Center for Defense Information)

gram between regulatory oversight audits will reduce, if not eliminate, commonly cited regulatory violations.

Interaction With the Regulatory Agency

As mentioned earlier, regulatory agencies are designed to prevent unnecessary radiation exposure to radiation workers and the public and to perform vital, public health functions guided by the agency's regulatory philosophy. The interaction between you and the oversight agency is crucial to a successful inspector/licensee relationship.

The licensee must become familiar with the regulatory goals of the oversight agency: to protect the health and safety of citizens and to protect the environment from the effects of radiation. Licensees may assist the regulatory agency in achieving these goals a number of different ways. Licensees should:

- Read and understand the regulations relating to their licensed use of radioactive material.
- Periodically perform an in-depth review of the important aspects of their radiation safety programs.
- Actively pursue modifications or improvements in licensed operations to maximize radiation safety and security.
- Provide basic radiation safety awareness training to all employees and provide frequent refresher training to radiation workers and management personnel who are ultimately responsible for the radioactive materials used under the license.
- Visit the regulatory agency's website frequently to learn about new or upcoming issues or regulations affecting their use of radioactive material.
- Build a quality working relationship with the individuals in the regulatory agency overseeing their licensed activities, and contact appropriate agency staff with questions related to licensing, storing, transporting or using radioactive material.

Licensees who are willing to take charge of their own radiation safety activities and demonstrate a level of performance in safety and compliance that provides reasonable assurance of a well-managed, safe operation often may be rewarded with an extension of inspection interval. The interval between inspections may be extended (lengthened) on the basis of satisfactory performance on the part of the licensee.

If licensees put more effort into maintaining a proactive radiation protection program, overall radiation safety will improve and the regulatory agency will recognize the extra effort.

Summary

The regulations governing the possession, use, storage, transportation and disposal of radioactive material are too numerous and complicated to completely commit to memory or to fully understand. It is imperative, therefore, that licensees and regulatory agencies build a solid cooperative relationship from person-to-person respect and communications, up to a broader scope of teamwork between the involved parties. In doing so, hopefully we can dispel myths of licensee paranoia and inspector ruthlessness that pollute the realm of licensees and regulatory agencies while working together to protect the health and safety of all citizens and to protect the environment from the potentially harmful effects of radiation.

Did you know?

The U.S. Centers for Disease Control and Prevention (CDC) reports 6.5 million cases of serious food-related illness each year, resulting in 10,000 deaths in the United States.

More extensive and uniform application of food irradiation has the potential to prevent many of these unnecessary illnesses and deaths.

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North Dakota Department of Health
Division of Air Quality
1200 Missouri Ave. Box 5520
Bismarck, N.D. 58506-5520
Phone: 701.328.5188

Dr. Terry Dwelle, State Health Officer
David Glatt, P.E., Environmental Health Section Chief
Justin M. Griffin, P.E., Environmental Engineer & Editor
Email address: jgriffin@state.nd.us

Several foods have been approved for irradiation in the United States, beginning with wheat flour in 1963. (Source: CDC)

North Dakota Radiation Control Program Website

The North Dakota Department of Health maintains its own website to promote public access to health-related information. The Radiation Control Program also maintains a website that contains information about the use of radioactive material in North Dakota.

www.ndhealth.gov/aq/rad

Our website contains electronic versions of the North Dakota Radiological Health Rules, radiation forms such as an "Application for Radioactive Material License," licensing guides, information notices, basic information about ionizing radiation and staff-member contact information.

If you have any questions or comments about the Radiation Control Program website, please contact Justin M. Griffin at 701.328.5188, or send e-mail to jgriffin@state.nd.us.

Access to Protected Health Information

The Department of Health may use protected health information, such as medical records, without written authorization of the individual when review of this information is required by law.

Code of Federal Regulations Part 45, Section 164.512 of the Health Insurance Portability and Accountability Act (HIPAA) allow a medical facility or other radioactive material licensees to release protected health information to a Radiation Control Program inspector without the individual's authorization. This is because the inspector is performing health oversight activities required by North Dakota Century Code and the Radiological Health Rules.

If you have questions regarding any rights included in HIPAA, you may contact the North Dakota Department of Health privacy official by phone at 701.328.2352.

Don't Let This Happen to You

On Dec. 30, 2004, an immediately effective order prohibiting involvement in licensed activities (for five years) was issued to an individual for deliberate misconduct. As the president, owner and radiation safety officer of the company, the individual deliberately failed to:

- Have sufficient number of qualified personnel present at temporary job sites
- Provide safety and dosimetry training to employees
- Conduct inspections and maintenance of industrial radiography equipment at specified intervals
- Maintain documentation of NRC-required inspection and maintenance records; and
- Provide complete and accurate information to the NRC.

In addition, an order revoking the company's NRC license was issued based on this particular individual's deliberate acts and omissions involving industrial radiography activities and the NRC's lack of reasonable assurance that public health and safety would adequately be protected by continuing activities under the license.

For the record...

Fox Television's popular Monday night "24" program involves a plot centered around the use of a black box called "the override" to remotely operate all 104 U.S. nuclear power plants via the Internet.

For the record, there is no such black box or suitcase for controlling nuclear power plants. Nor are control systems at the plants accessible via the Internet. (Source: U.S. NRC)

"24" is merely entertaining fiction.

For additional information about the department's HIPAA policy, visit www.ndhealth.gov/ndhd/admin/hipaa/.